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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,570	08/16/2006	Michael Betz	BP/G-32576A/BCK	5942

1095 7590 03/12/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
YOUNG, HUGH PARKER	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,570	BETZ ET AL.	
	Examiner	Art Unit	
	Hugh P. Young	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,14,15 and 17-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,14,15 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Jan. 7, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the first Office action on the merits of application No. 10,520,570. There are nineteen claims pending, all of which are under consideration. Claims 11, 13, 16 and 17 were cancelled by Applicant during amendment.

Objections to the specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 22 claims propylene glycine as a limitation but is not disclosed in the Specification.

Objections to the claims

2. Claim 22 is objected to because of the following informalities: the phrase "essentially consisting of" is used rather than the standard "consisting essentially of," which lead to confusion when interpreting the meaning and scope of the claim. Appropriate correction is required.

3. Claim 22 recites the limitation "propylene glycine" in the third line. There is insufficient antecedent basis for this limitation in the claim. Claim 22 is dependent from claim 1, which claims glycine, not "propylene glycine."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-10, 12, 14, 15, and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al, US Patent 5,763,394, issued June 9, 1998 (filed July 29, 1993 as PCT/US93/07149) as applied to claims 1-10, 12, 14, 15, and 18-23 above.

7. O'Connor et al describe in their claim 9 a human growth hormone formulation comprising human growth hormone (referred to hereafter as hGH) in the concentration range of 1-20 mg/ml, contained in a buffer system providing a pH of 5.5-7, a non-ionic surfactant, a neutral salt. At column 3, lines 27-32, the mixture has no requirement for glycine, however glycine is "an optional component of the aqueous formulation." They omit it from their claimed formulation because it provides "less advantage in the aqueous formulations hereof" and allude to the fact that glycine is more advantageous in preparations that have at some point been lyophilized. The range of hGH claimed by O'Connor et al overlaps the range claimed in the instant claim 1 and completely encompasses the preferred range and single value in the instant claims 2 and 3. O'Connor et al discuss the role of glycine in the Background of their invention in column 1 of the '394 patent, citing commercial preparations that contain glycine (column 1 lines,

30 and 42) and column 2, line 7). The latter reference is in the context of O'Connor et al's formulation having the unexpected advantage of being more stable with glycine absent, contrary to the common practice in the art. O'Connor et al do recite the value of 5 mg/ml in the abovementioned line 32, column 1 as being part of the commercially marketed Humatrope® formulation, this value being at the low end of the range claimed in the instant claim 5. O'Connor et al describe their preferred embodiments, column 4, lines 19-39, as having quantities of components somewhat flexible within ranges and that the materials recited in the disclosure are interchangeable within the component categories, allowing for instance, for additional buffering agents.

8. The instant claim 6 claims that the instant composition should be "substantially isotonic" and O'Connor et al state, in lines 27-28, column 4, that "Preferably, the formulation is isotonic and sterile." O'Connor et al, in their disclosure, column 4, lines 46-49, state that the buffers for their composition include phosphate, citrate, and acetate, comprising three of the buffer choices from the instant claim 7, and the phosphate buffer of the instant claim 8; O'Connor et al further claim phosphate buffer in their claim 16. O'Connor et al, column 3, lines 46-49, state that suitable buffers are formulated in the range of "about 2 mM to about 50 mM" and when formulated with their other components the final mixture has a pH value of "about pH 6" (their claims 7 and 15) which, in conjunction with their claimed pH range of 5.5-7 in their claim 1 is similar to and encompasses the pH range in the instant claim 1 and the value of pH 6.2 in the instant claim 21.

9. The instant claims 1 and 12-15 claim a non-ionic surfactant, poloxamer and polysorbate being specified in claims 12-15. O'Connor et al claim Poloxamer 188 in their claims 2,3, 10 and 11 and Polysorbates in their claims 4, 5, 12 and 13. O'Connor et al state a broad range of surfactant concentrations, from 0.1% to 5% w/v, with 0.1% to 1% w/v preferred (column 3, lines 33-45), overlapping the instant claims. The instant claim 18 claims preservatives, and claims 19 and 20 specify benzyl alcohol. O'Connor et al state (column 3, lines 52-56) that their list of acceptable preservatives includes several of those from the instant claim 18, most particularly phenol and benzyl alcohol, the latter cited in a range of 0.7-1% w/v, overlapping the range of the instant claim 20.

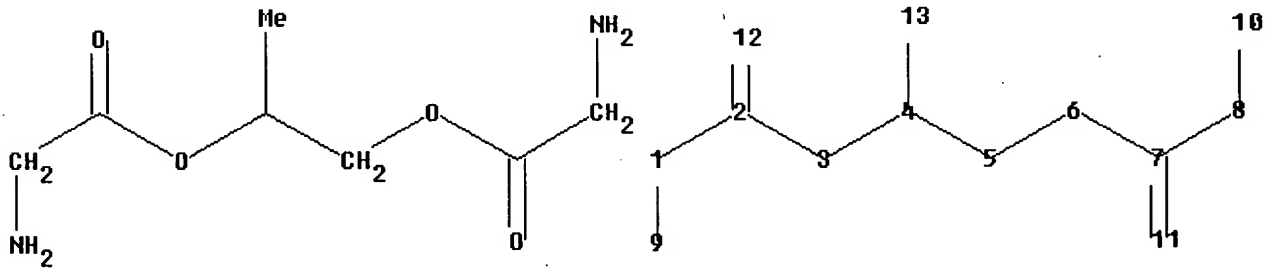
10. In summary: there is a prima facie case of obviousness in regards the instant claims when compared to the prior art cited above (O'Connor et al, US Patent 5,763,394). The prior art discloses all of the aspects and limitations of the instant invention, either specifically, such as the use of the surfactant Poloxamer 188, or with ranges of values that encompass or overlap those claimed by Applicant, such as the quantities of the active ingredient hGH, or as alternative choices of materials to be used to achieve the same result, such as the choice of buffer system or preservative. The claimed ranges and values for the amount of glycine that are greater than those typically found in the art are obvious in that it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case claim 22 claims the component or ingredient "propylene glycine" in line 3. There is no antecedent basis for this elsewhere in the disclosure, neither in claim 1 from which it depends or in the main body of the Specification. The name "propylene glycine" was entered in the ChemDraw software package and a single structure was created and displayed. The structure (both exact and broad) as below and the name "propylene glycine" were both searched in Chem Abstracts Registry:



The term "propylene glycine" is not found in the Chemical Abstracts Registry, nor is it known in any of the reference materials common to the pharmaceutical or pharmacological arts. The material claimed, "propylene glycine," is not known in the art nor defined by Applicant.

Art of record

13. O'Connor et al, US Patent Publication 2003/0013653, published January 16, 2003 (filed July 1, 2002).

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D. GAU 1654

JON WEBER
SUPERVISORY PATENT EXAMINER